IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KING DRUG COMPANY OF FLORENCE, INC. *et al.*, **v.** **Cephalon, Inc., *et al.*,**	**Civil Action No. 2:06-cv-01797-MSG**
UNITED HEALTHCARE SERVICES, INC. **v.** **Cephalon, Inc., *et al.*,**	**Civil Action No. 2:17-cv-00555-MSG**

PLAINTIFFS' OMNIBUS MOTIONS *IN LIMINE* NOS. 14-22

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This omnibus motion is filed on behalf of the plaintiffs in the *King Drug* action ("King Drug Plaintiffs") and United Healthcare Services, Inc. (hereinafter "United") (collectively, "Plaintiffs").[1]

Motion *in Limine* No. 14: To Preclude Ranbaxy From Stating or Implying that the Other Named Defendants Were Not Sued and/or that Other Generic Manufacturers Were "Freeriding" on Ranbaxy's Efforts to Invalidate the '516 Patent

During Ranbaxy's opening and closing statements at the 2017 trial, counsel for Ranbaxy stated the following concerning Ranbaxy's presence as the only defendant at trial:

> [T]hey are suing us. Not suing the other generics here in the case, not trying the case here, not suing Cephalon here.
>
> The reason we are here is Plaintiffs have sued my client alone here, arguing that we delayed the entry of generic modafinil onto the market.
>
> Cephalon is not here. Ranbaxy is here, one of the four settlers….
>
> I want to focus on how [plaintiffs] tried their case. They tried a case against Cephalon. Cephalon is not a party to this case.

See Ex. A (6/14/2017 Tr. at 91:9-11; 92:2-5)(opening statement); Ex. B (7/6/2018 Tr. at 25:15-16; 35:10-12)(closing statement). *See also* Ex. B (7/6/2018 Tr. at 39:8-17) (telling

[1] In 2015, the (then-class) King Drug Plaintiffs filed numerous motions *in limine*, including but not limited to Motions *in Limine* Nos. 1-13. *See* Dkt Nos. 909-915 (all docket references herein are to the King Drug docket unless otherwise noted). For ease of reference, Plaintiffs have styled the instant motions *in limine* as Nos. 14-22. For the avoidance of doubt, Plaintiffs join in all other previously decided motions *in limine* filed by any plaintiff either in this case or the related *In re Modafinil Antitrust Litigation* cases for purposes of any appeals in its case. For purposes of appeal, Plaintiffs further preserve and do not waive their rights to make any argument previously made by any plaintiff in this case or in the related *In re Modafinil Antitrust Litigation* cases, whether or not ultimately adopted by the Court, and whether such argument was made in writing or presented orally. Although Plaintiffs continue to assert each of the arguments, motions, oppositions and issues that have been previously presented to the Court in the related *In re Modafinil Antitrust Litigation* cases, Plaintiffs recognize that the Court has already resolved many of them. Rather than seek reconsideration of any of those rulings, Plaintiffs agree not to relitigate them in this Court (other than those specifically raised herein, at the pretrial conference, or at trial) provided that each of them is preserved for appeal.

jury that "my client is supposed to shoulder the entire responsibility in this case" while Apotex "hid in the shadows").

Counsel for Ranbaxy also suggested during opening and closing statements that Ranbaxy was the only generic manufacturer that had litigated the '516 patent and that it was exposed to damages simply by virtue of doing so:

> We got on the market three years before the expiration of the patent. And the case that the plaintiffs put on is a complaint that we didn't do it fast enough for them, spending the money ourselves while our competitors sat there and let us spend the money to help them get on the market.
>
> If I lose that patent case, Ranbaxy alone gets nailed with the damages. If Ranbaxy wins the patent case, they invalidate the patent and all generics can run and compete with them. So those other generics are not sharing the risk of loss, they are only getting the upside because they are not in the litigation fighting the patent.
>
> We call it free riding. In other words, another generic is free riding on the efforts of, in this case, Ranbaxy, to take all of the risk, knock the patent out, and everybody comes in on a free ride.
>
> My opponents say that Ranbaxy by taking all the risk and bearing all the costs….they just did not do enough……by taking all that risk, spending the money on lawyers, it was not enough…..you should have done more while they sat on the sidelines and did not incur that risk…..they want it all while they sit on the sidelines and don't participate and incur that same risk.

See Ex. A (6/14/2018 Tr. at 87:3-8; 134:17-23; 135:1-5)(opening statement); Ex. B (7/6/2018 Tr. at 34:14-35:6)(closing statement).

Such statements erroneously suggested and implied, if not directly asserted, that Ranbaxy was, at the time of its settlement of the underlying patent litigation with Cephalon, alone in its efforts to invalidate the '516 patent (and upon pain of damages), and further, was being singled out by plaintiffs at the 2017 trial (the "2017 Plaintiffs") for not continuing its patent challenge.

First, as the Court and all parties are aware, Plaintiffs (like the 2017 Plaintiffs) also sued Cephalon, Teva, Mylan, and Barr. Indeed, during the 2017 trial, the Court *sua sponte* observed the impropriety of Ranbaxy statements concerning its presence at trial as the sole defendant:

> I think that you said a couple of things – and I wrote a couple of quotes down – that either clearly stated or directly implied that the three other generics or Cephalon were never parties to this case, and I worry about that a little bit because, if it needs explaining, then we have to wander into the settlement issue...

See Ex. A (6/14/2017 Tr. at 97:21 – 98:2).

Though a curative instruction[2] was subsequently given to the jury in that trial, Plaintiffs respectfully submit that the instruction was not sufficient to overcome the improper and inaccurate assertion that Ranbaxy was singled out, and that none of the other parties to the settlements with Cephalon was (or will be) called to account for its actions. Further, despite the Court's comments and curative instruction during openings, counsel for Ranbaxy repeated similar misleading statements during closing statements.

Second, Ranbaxy's "free riding" assertions are factually inaccurate and wildly misleading. Ranbaxy was not the only entity that litigated the patent and thus was not the only one "spending the money" while other generics "sat there." And of course, apart from the litigation efforts of the first filers, Apotex was the generic that litigated the patent case to verdict and ultimately invalidated the patent. Separately, as the second first-filer to settle with Cephalon (*i.e.*, after Teva but before Mylan and Barr) Ranbaxy itself was "freeriding," because if Mylan

[2] The curative instruction was as follows: "I just wanted to remind you that the only defendant that is on trial here is Ranbaxy, and so concern yourself with that agreement and don't concern yourself with the status of Cephalon and the other three generics. You will probably have to hear and you have already heard about their involvement in the settlements, but I just want to remind you the only defendant, generic defendant that is on trial here is Ranbaxy, okay." *Id.* at 110:18 – 111:1. Respectfully, this served to underscore that Ranbaxy was "the only defendant that is on trial," without addressing Ranbaxy's misleading suggestion that there were never any *other* defendants.

and/or Barr refused to settle and entered the market earlier, Ranbaxy was automatically permitted to enter at that same earlier date under its contingent launch provision. Finally, because Hatch-Waxman litigation cannot and does not result in any damages, even if it were to lose the patent case, Ranbaxy would face zero risk of damages simply by litigating the patent.

While the 2017 Plaintiffs objected to these mischaracterizations during the 2017 trial and the Court agreed that Ranbaxy was not permitted to say that other generics "sat on their hands and did nothing" during the remainder of its opening statement, the Court declined to give a curative instruction on the basis that the trial had just begun. *Id.* at 105:2-107:25. Ranbaxy then reiterated its "freeriding" argument during its closing statement.

Because the aforementioned statements and implications pose a substantial risk of unfair prejudice, as well as confusing or misleading the jury, Ranbaxy should be precluded from stating, suggesting, or implying at the upcoming trial that: (1) Ranbaxy was the only entity sued by Plaintiffs[3]; (2) Ranbaxy litigated the patent alone and/or that other generic manufacturers "relied on" Ranbaxy or "sat around;" and (3) Ranbaxy would have incurred damages if it had lost the patent litigation. Furthermore, in the event that such statements or implications are made to the jury, Plaintiffs request that the following instructions be given, as appropriate:

- That Ranbaxy was not the only generic manufacturer who litigated the patent and that another generic manufacturer, Apotex, also challenged the patent, and invalidated it.
- That Ranbaxy was not liable for any infringement damages simply by litigating the patent case, even if Ranbaxy had lost.

[3] Plaintiffs will also be requesting that the Court issue a preliminary instruction concerning Ranbaxy's presence as the sole defendant at trial.

Motion *in Limine* No. 15: To Preclude Ranbaxy From Asserting That It Never Received Final Approval From the Food and Drug Administration

Ranbaxy should be precluded from arguing that it did not receive final approval from the FDA to launch generic Provigil for two reasons. First, this Court previously ordered Ranbaxy - *twice* - not to make that argument. Second, there is no factual basis in the record that some theoretical issue would or could have prevented final approval between February 2004, when Ranbaxy received tentative approval from FDA, through December 2006, when Plaintiffs assert Ranbaxy would have obtained FDA final approval absent the settlement with Cephalon.

During fact discovery, King Drug Plaintiffs requested documents concerning Ranbaxy's manufacturing capacity, capabilities, and current good manufacturing practices ("cGMP"). After meeting and conferring, on October 28, 2010, Ranbaxy pledged it would not assert "a defense that it could not launch its generic Provigil product due to capacity restraints or cGMP issues," and, accordingly, deemed plaintiffs' requests "moot." *See* Ex. C (10/28/2010 Ranbaxy Letter). *See also* Ex. D (6/26/2017 Tr. at 11:1-15)(reciting 10/28/2010 Ranbaxy Letter). Based on this agreement, King Drug Plaintiffs and Ranbaxy avoided time-consuming and expensive discovery on these issues.

Before the February 2016 trial was stayed, King Drug Plaintiffs (among other former plaintiffs) filed Motion *in Limine* No. 5, which sought to prevent Ranbaxy from arguing defenses based on capacity, capabilities, and cGMP issues. *See* Dkt Nos. 909, 911. Ranbaxy opposed this Motion, arguing that its ability to obtain FDA final approval and launch was at issue and vaguely asserted that "many different issues . . . may arise between the grant of tentative approval and launch." *See* Dkt No. 947.

In May 2017, the Court granted Motion *in Limine* No. 5, stating:

> [I]f [Ranbaxy is] permitted to present evidence and argument regarding [its] manufacturing capacity, Plaintiffs would be prejudiced. [Ranbaxy] expressly

> stated that discovery on these issues was unnecessary as they did not intend to present this evidence in their defense. Plaintiffs were entitled to rely on these representations in completing discovery and preparing for trial. As such, Plaintiffs' Motion in Limine Number 5 will be granted.

See Case No. 06-02768, Dkt No. 1164.

Despite this ruling, during opening statements at the 2017 trial, Ranbaxy's counsel said Ranbaxy "never received FDA final approval of [its generic Provigil application]; therefore; it could never launch [generic Provigil]." *See* Ex. A (6/14/2017 Tr. at 94:5-7). Ranbaxy also argued and elicited testimony that many types of issues can theoretically prevent tentative approval from becoming final approval. *See, e.g.*, Ex. D (6/26/2017 Tr. at 14:7-11, 15:12-13, 17:4-9, 18:15-20).

As a result of, *inter alia*, Ranbaxy's counsel's opening statement, 2017 Plaintiffs filed a Second Motion *in Limine* Regarding Ranbaxy's cGMP Defense. *See* Case No. 06-2768, Dkt No. 1240. The Court, in accordance with the reasons stated in the record, again ordered Ranbaxy not to argue or elicit testimony that Ranbaxy did not receive final FDA approval. *See* Case No. 06-02768, Dkt No. 1249. *See also* Ex. E (6/27/2017 Tr. at 113:1-8 ("[Y]ou cannot say or elicit testimony that Ranbaxy never got FDA approval.").

It may be that, as a theoretical matter, a generic applicant with tentative approval may not later be able to obtain final FDA approval due to such issues as changes in the science-based portion of a generic application occurring after tentative approval. If such a change occurs, the FDA will issue what is known as a "deficiency" to the applicant – *i.e.*, the FDA issues a "deficiency" in the form of a letter notifying the applicant of the specific issue and the means by which to address the issue.

Here, *there were no such deficiencies issued by the FDA to Ranbaxy between the time that Ranbaxy received tentative approval in February 2004 and December 2006,* when Plaintiffs allege Ranbaxy would have obtained final approval absent the settlement with Cephalon and

upon expiration of the regulatory exclusivities pertaining to Provigil. As a result, Ranbaxy did not in the 2017 trial, and cannot now, identify any facts or bases (*i.e.,* any deficiencies noted by FDA) on which to argue that the FDA would have refused to grant Ranbaxy final approval of its application on or around December 24, 2006, upon expiration of the Provigil's regulatory exclusivities had it merely asked for it. Mr. Venkatachalam Krishnan, Ranbaxy's former director of sales and marketing for the United States, testified that Ranbaxy expected to receive FDA final approval upon expiration of those exclusivities. *See* Ex. F (6/21/2017 Tr. at 67:9-15).

In actuality, the reason that Ranbaxy ultimately never received FDA final approval for generic Provigil was because cGMP issues at its Dewas manufacturing plant in India resulted in Ranbaxy entering into a Consent Decree with the Department of Justice on behalf of the FDA on January 25, 2012 – years after the events at issue here. *See* Ex. G (U.S. Dept. of Justice, U.S. Files Consent Decree for Permanent Injunction Against Pharmaceutical Ranbaxy Laboratories, Jan. 25, 2012 (available at https://www.justice.gov/opa/pr/us-files-consent-decree-permanent-injunction-against-pharmaceutical-ranbaxy-laboratories)). Pursuant to the Consent Decree, Ranbaxy withdrew its generic Provigil application with FDA on January 26, 2012. The cGMP issues that later led to the withdrawal of Ranbaxy's generic Provigil application are issues that Ranbaxy previously stipulated out of this case and that the Court precluded Ranbaxy from raising.

In sum, Ranbaxy should be precluded from arguing that it did not receive final approval from the FDA to launch generic Provigil because: (a) to suggest that there might have been deficiencies that would have prevented Final Approval would be rank speculation for which Ranbaxy has no factual basis; and (b) to raise the fact that Ranbaxy did not actually receive Final Approval (which stemmed from cGMP) would be to raise the very issues that Ranbaxy stipulated

it would not raise and which the Court ordered that Ranbaxy could not raise. Argument of this type would pose the potential for severe prejudice to Plaintiffs, and, indeed, would risk a mistrial.

Consequently, Plaintiffs request that the Court extend its 2017 rulings prohibiting testimony that Ranbaxy never received FDA final approval to this trial and to preclude Ranbaxy from making vague, confusing, and prejudicial arguments and eliciting testimony that unspecified reasons (*e.g.*, "many reasons," "many things," or "a number of factors") could have prevented final approval when no such reasons exist in the record and such broad statements necessarily encompass cGMP issues.

Motion in Limine No. 16: To Preclude Argument or Evidence Concerning Any Plaintiff's Size

Ranbaxy may seek to portray Plaintiffs, either individually or collectively, as large and/or well-funded. Indeed, Ranbaxy has listed SEC filings pertaining to various plaintiffs among its proposed exhibits – exhibits which appear to have no other purpose that to highlight that certain plaintiffs are large companies. However, any argument or evidence concerning any plaintiff's size or financial condition is entirely irrelevant to any issue at trial and should therefore be excluded pursuant to Rule 401. *See, e.g., Farris v. Int'l Paper, Inc.,* 2014 U.S. Dist. LEXIS 162335, at *65-67 (C.D. Cal. Nov. 17, 2014)(in wage dispute, excluding party's "profits, financial condition, net worth or size" as irrelevant to claims and defenses at issue); *Martin v. Interstate Battery Sys. of Am.,* 2016 U.S. Dist. LEXIS 109837, at *4-5 (N.D. Okla. Aug. 18, 2016)(disallowing any reference to party's "size, net worth, revenues, profits, or financial condition" until punitive damages phase).

Motion *in Limine* No. 17: To Permit Plaintiffs' Expert Dr. Harry Brittain to Offer Opinions on the Ultimate Issues of Patent Validity and Infringement and to Exclude any References to Prior Rulings Excluding an Expert's Testimony in Unrelated Cases

Plaintiffs seek a pretrial ruling that Plaintiffs' technical expert, Dr. Harry Brittain, may testify at trial regarding his opinions on the ultimate issues of patent validity and infringement.

Prior to the *Daubert* phase of this case, no dispute existed among the parties that technical experts were entitled to opine on the ultimate issues of patent validity and infringement. Plaintiffs and Defendants both proffered reports from experts who opined on the ultimate issues of patent validity and infringement, and Defendants' experts opined precisely and specifically on these issues. *See, e.g.*, Ex. H (2011 Antonietti Report ¶ 10 ("It was reasonable to assert that Mylan's, Ranbaxy's, Barr's, and Teva's modafinil products infringe the claims of the '516 patent literally or under the doctrine of equivalents, and ***it remains my opinion that these products do so infringe***.")) (emphasis added); Ex. I (2011 Cooper Report ¶ 7 ("Based on my review, it is my opinion that the '516 patent is valid. . . ."); *Id*. ¶¶ 28, 34 ("[I]t is my opinion that Cephalon did not derive the claimed invention from Lafon. . . . Dr. Grebow's inventor declaration that he believed he was the 'original first and joint inventor' of the subject matter of the '516 patent was absolutely correct.")).

During the *Daubert* phase of this case, Plaintiffs moved to exclude any opinions that the '516 Patent was valid or infringed. The basis for Plaintiffs' motion was *not* that these types of opinions are improper legal conclusions. Rather, the basis for Plaintiffs' motions was that opinions that the '516 Patent are valid or infringed conflict with this Court's fully affirmed 2011 opinion in the *Apotex* case, and are therefore unreliable and do not fit the facts of this case.[4] The Court granted Plaintiffs' motion, holding that Defendants' "experts will not be permitted to opine

[4] *See Apotex, Inc. v. Cephalon, Inc.*, 2011 U.S. Dist. LEXIS 125859 (E.D. Pa. Oct. 31, 2011), *aff'd*, 500 Fed. Appx. 959 (Fed. Cir. 2013).

that the patent is presently valid, or to adopt as true legal standards that directly conflict with the conclusions of law established by my validity ruling in the Apotex patent litigation." *See* Dkt No. 887 at 31-32. Nothing in this ruling, however, precluded Dr. Brittain from offering his opinions, which are completely consistent with this Court's rulings.

Presumably cognizant that the rationale for this Court's *Daubert* opinion applied to Defendants' experts (whose opinions directly conflict with this Court's patent rulings) but not to Dr. Brittain, Defendants subsequently moved *in limine* seeking to limit Dr. Brittain from testifying on validity and infringement and seeking that he be subject to the "same limitations set forth in the *Daubert* ruling for Defendants' corresponding experts." *See* Dkt No. 903-1. Plaintiffs, however, explained that the basis for excluding Defendants' experts' opinions on validity and infringement—namely, that they contradict this Court's now-affirmed rulings on the '516 Patent—was plainly inapplicable to Dr. Brittain. *See* Dkt No. 939 at 3-5. Just prior to the 2017 trial, the Court denied Defendants' motion *in limine* as moot. *See* Case No. 06-cv-2768, Dkt No. 1209.

During the 2017 trial, Ranbaxy then took a new tack. Despite having sponsored expert opinions on the ultimate issues of patent validity and infringement, Ranbaxy shifted towards characterizing such opinions as improper "legal conclusions."

MR. VERROCCHIO:	Your Honor, I don't have any concerns about [Dr. Brittain's] qualifications as to the science. However, if he wanders into areas that are legal conclusions, I will have an objection.
THE COURT:	Yes. That is more of a substantive testimony.
MR. VERROCCHIO:	Yes.

See Ex. J (6/16/17 Tr. at 10:15-21).

As Dr. Brittain's testimony developed, this Court asked whether Apotex and the Retailers would agree that Dr. Brittain would refrain from testifying on the ultimate issues of whether there was "infringement" or the patent was "invalid":

> THE COURT: Maybe if we set out the parameters, as I hopefully remember, they are from prior rulings, and see if we can all agree. I think it should be that you can't ask him legal opinions like is there -- based on your review of the particle size in Ranbaxy's . . . .
>
> MR. SODIKOFF: He is --
>
> THE COURT: Let me finish my thought. ***He can't say based on my review of particle there was infringement or there was invalid patent. He can't say that. Do you agree to that?***

Id. at 19:8-18 (emphasis added). Apotex's counsel agreed that Dr. Brittain was "not going to say that." *Id*. at 19:19-20. Subsequently, the Court ruled that Dr. Brittain "can't say who invented what" because doing so "gets too close to a legal opinion." *Id.* at 24:9-15.

At the upcoming trial, Dr. Brittain should be able to testify as to his opinions on the validity and infringement of the '516 Patent for several reasons.

First, courts routinely allow experts qualified as persons of ordinary skill to offer expert testimony on the ultimate issues of infringement and validity. Fed. R. Evid. 704 ("An opinion is not objectionable just because it embraces an ultimate issue."). Patent infringement is a question of fact. *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1186 (Fed. Cir. 2014). As such, "testimony on the ultimate issue of infringement is permissible in patent cases." *Symbol Technologies, Inc. v. Opticon, Inc*., 935 F.2d 1569, 1575 (Fed. Cir. 1991). *See also Snellman v. Ricoh Co.*, 862 F.2d 283, 287 (Fed. Cir. 1988), *cert. denied*, 491 U.S. 910 (1989) ("Although claim interpretation is a question of law, expert testimony is admissible ... to give an opinion on the ultimate question of infringement."); *Rohm and Haas Co., v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997) (noting that, in a patent infringement case, that "an expert may testify to

the ultimate issue" of infringement). Moreover, some validity defenses are questions of fact, whereas others are mixed questions of fact and law. For example, anticipation is a question of fact, *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 471 F.3d 1369, 1375 (Fed. Cir. 2006), whereas obviousness is a question of law premised on subsidiary questions of fact, *Arctic Cat Inc. v. Bombardier Recreational Prod. Inc.*, 876 F.3d 1350, 1358 (Fed. Cir. 2017). Although some defenses like obviousness are nominally considered questions of law, courts often allow expert testimony on these ultimate issues as well. *Voter Verified, Inc. v. Premier Election Solutions, Inc.*, 2010 U.S. Dist. LEXIS 80087, at *15-16 (M.D. Fl. August 9, 2010) ("Shamos may give his expert opinion on the ultimate issue of a patent's invalidity due to obviousness or anticipation.") (citing *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985)).[5]

The Federal Circuit's decision in *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356 (2008) is instructive. *Sundance* dealt with the admissibility of testimony on patent validity and infringement *from a patent law expert who did not possess technical expertise in the scientific field of the patent*. *Id*. at 1361-62. While the Federal Circuit held that such expert testimony was inadmissible, it made clear that similar testimony from a technical expert would pass muster. For example, the Federal Circuit explained that "it was an abuse of discretion for the district court to permit [the expert] to testify as an expert on the issues of noninfringement or invalidity," but only "because [he] was never offered as a technical expert, and in fact was not qualified as a technical expert." *Id*. at 1362. Likewise, it held that "it is an abuse of discretion to permit a witness to testify as an expert on the issues of noninfringement or invalidity *unless that*

[5] *Cary Oil Co., Inc. v. MG Refining & Marketing*, 2003 U.S. Dist. LEXIS 6150, at *13 (S.D.N.Y. April 11, 2003) ("[T]he Second Circuit has held that "[e]xperts may testify on . . . mixed questions of fact and law.") (internal citation omitted).

witness is qualified as an expert in the pertinent art." *Id.* at 1363 (emphasis added). Although it may nominally be a question of law, whether to admit expert testimony from "a qualified technical expert . . . as to the ultimate question of obviousness is of course left to the discretion of the district court." *Id.* at 1364 n.6.

It is true, of course, that Dr. Brittain applied the law to the facts in arriving at his opinions on validity and infringement. But again, there is nothing improper with such testimony. As one court explained,

> Under Federal Rule of Evidence 704, an expert witness is permitted to testify in the form [of] an opinion as to an 'ultimate issue of fact.' In this case, such ultimate issues of fact include whether the claims of the '112 patent were infringed by Gentex products, whether those claims are valid, whether Donnelly meets the legal requirements to be awarded lost profit damages, and the amount of royalty which would be reasonable in this matter. Nevertheless, the experts may not testify as to what the law is since it is the Court's job to instruct the jury as to what the law is. Therefore, ***such experts must walk a fine line: they must give their expert opinions on ultimate issues of fact, while explaining their own understandings of the law, but without purporting to give expert opinions as to what the law is***.

Donnelly Corp. v. Gentex Corp., 918 F. Supp. 1126, 1137 (W.D. Mich. 1996). Dr. Brittain does just that: he gives his expert opinion on ultimate issues of fact, applying the law, and without purporting to give an expert opinion as to what the law is.

Second, even if there were a proscription on the aforementioned testimony in patent cases – and there is not – this is an antitrust case in which patent infringement and validity are not ultimate issues that the jury will be asked to decide. Presumably, Ranbaxy's rationale for seeking to preclude a technical expert from opining on the ultimate issue of infringement or invalidity in the 2017 trial was that it would usurp the role of the jury in making factual findings or invade the province of the court in rendering legal conclusions. *See, e.g.*, *Sundance, Inc.,* 550 F.3d at 1364 ("The court, in its role as gatekeeper, must exclude expert testimony . . . which invades the

province of the jury to find facts and that of the court to make ultimate legal conclusions."). However, patent infringement and patent invalidity are not ultimate issues to be decided in this case. The Court has already ruled in 2017 that Ranbaxy's patent pleadings, which alleged and explained Ranbaxy's theory of non-infringement and invalidity, are admissions, and expert testimony from Dr. Brittain on those same issues is perfectly appropriate. Such testimony will not invade the province of the jury or the court. Rather, it will aid the jury in understanding the significance of the statements made in Ranbaxy's own pleadings and briefs, tying the factual statements to the legal result, *i.e.*, that the patent was not infringed and that the patent was invalid. *See* 29 Charles Alan Wright & Victor James Gold, Federal Practice & Procedure § 6284 (2008) ("[T]he admissibility of opinion testimony that may involve legal conclusions ultimately rests upon whether that testimony helps the jury resolve the fact issues in the case."). Because Dr. Brittain's testimony will assist the trier of fact in understanding the evidence, Dr. Brittain should be permitted to testify about the ultimate conclusions as to infringement and invalidity.

Separately, Plaintiffs seek a pretrial ruling excluding any references to any prior rulings in unrelated cases excluding Dr. Brittain's testimony. During the 2017 trial, Dr. Brittain was asked during cross-examination about another court's ruling in an unrelated case that allegedly excluded his testimony. *See* Ex. J (6/16/2017 Tr. at 84:12-86:23). In response to 2017 Plaintiffs' objection, defense counsel withdrew the line of questions rather than have this Court rule on the objection. *Id.* at 88:1-23. Plaintiffs now request a ruling to preclude any references, evidence, testimony, arguments regarding, or inquires attempting to elicit testimony regarding the fact that testimony or opinions offered by Dr. Harry Brittain in an unrelated case may have been excluded. The issues in the other case do not implicate the same technology in this case or pertain to the same patent, and therefore prior testimony and opinions offered by Dr. Brittain in

other cases are entirely unrelated to the dispute at hand and are not probative of any fact at issue in this case. Such prior cases are inadmissible as irrelevant under Federal Rule of Evidence 402. Similarly, because they risk unfairly prejudicing the jury against Plaintiffs, such testimony is also inadmissible under Federal Rule of Evidence 403.

Motion *in Limine* No. 18: To Preclude Ranbaxy From Asserting That "Risk Aversion" or "Litigation Uncertainty" is a Permissible Procompetitive Justification

Ranbaxy cannot defend its agreement to delay entry by citing "risk aversion" or "litigation uncertainty." Plaintiffs have not brought this case because Cephalon and Ranbaxy settled patent litigation, but because Ranbaxy exploited its discovery of Cephalon's fraudulent conduct by demanding a payment to abandon its meritorious defenses to the patent litigation. Accordingly, any procompetitive justification that Ranbaxy offers must explain the *payment for delay*, not the fact of settlement. *Actavis* itself recognizes that Hatch-Waxman cases may be settled without reverse payments. *See FTC v. Actavis, Inc.*, 133 S.Ct. 2223, 237 (2013). Ranbaxy's own expert economist at the 2017 trial agreed. *See* Ex. J-1 (6/30/2017 Tr. at 94:1-4) ("Q. And you also agree, don't you, Dr. Bell, that Hatch-Waxman pharmaceutical cases can be settled without reverse payments being made? A. I believe so, yes."). Because a no-payment settlement would permit Ranbaxy to avoid the risk of litigation, Ranbaxy cannot justify the *payment* as a way to avoid the risk of the litigation. Moreover, the fact that a patentee may pay a generic handsomely to forego a patent challenge is the core concern of *Actavis* and the antitrust laws and can therefore never be considered a "procompetitive" benefit. When a patentee uses its monopoly profits to pay a generic challenger a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market, both the patentee and generic win – just as parties to a price-fixing agreement win – but consumers lose. *Id.* at 154.

Not only is it an impermissible rationale, it can create jury confusion by injecting a factor that is irrelevant to their application of the law to the facts.

This Court previously stated that "the Generic Defendants may present expert testimony regarding their own litigation uncertainty in providing procompetitive justifications for the reverse-payment settlements." Dkt. No. 861 (Opinion at 17). The Court likewise declined to exclude expert opinions concerning the litigation risk that Ranbaxy faced and how resolution of the risk of litigation uncertainty vis-à-vis settlement provides purported procompetitive benefits. *See* Dkt. No. 887 (Opinion at 39-40).

However, since the Court's initial decisions and last year's trial the Third Circuit has made clear that an antitrust defendant must "justify a large reverse payment." *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 256 (3d Cir. 2017). *See also id.* ("[D]efendants have the burden of justifying the rather large reverse payment here"). The defense Ranbaxy plans to offer is speculative, not tied to the facts of the case, and directly contrary to the dictates of *Actavis* and governing Third Circuit law.[6]

Under the rule of reason, any pro-competitive justification that is offered by the defendant must explain the challenged terms, namely the payment in exchange for foregoing the patent challenge. *See, e.g.*, *Lipitor*, 868 F.3d at 256 (antitrust defendant must "justify a large reverse payment"); *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 412 (3d Cir. 2015) ("the burden then shifts to the defendant to show 'that legitimate justifications are

[6] To the extent necessary, Plaintiffs move for reconsideration of the October 5 and November 5, 2015 orders. Reconsideration is warranted for: (1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court granted the motion for summary judgment; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice. *Max's Seafood Cafe ex rel. Lou-Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999). All three apply here.

present, *thereby explaining the presence of the challenged term* and showing the lawfulness of that term under the rule of reason'") (quoting *Actavis*, 570 U.S. at 156) (emphasis added).

Ranbaxy's desire to avoid litigation risk is not served by the alleged reverse payment to delay competition. "An allegedly legitimate objective is, of course, entirely immaterial unless it is served by the challenged restraint." Phillip E. Areeda & Herbert Hovenkamp, ANTITRUST LAW ¶ 1505a. The logic of this principle is straightforward: "If the defendants have a procompetitive justification, it must have been a motivating factor for the restraint, and the defendants should be able to establish it rather easily." Herbert Hovenkamp, *The Rule of Reason*, 70 FLA. L. REV. 81, 107 (2018). Thus, well-established rule-of-reason precedent requires a defendant to show that the challenged conduct furthered a legitimate, procompetitive objective. When defendants fail to establish the requisite link, courts reject the justification even if the proffered benefits are otherwise legitimate.

Ranbaxy would ignore this well-established requirement because the challenged restraint is contained in a broader agreement. But a defendant's obligation to connect the challenged restraint to the claimed procompetitive objective applies equally in that context. In *NCAA*, the challenged restraints on football telecasts were part of a broader set of rules agreed to by member colleges. The Supreme Court noted that it was "reasonable to assume that most of the regulatory controls of the NCAA are justifiable means of fostering competition among amateur athletic teams and therefore procompetitive." 468 U.S. at 117. But the Court focused narrowly on whether the challenged restrictions on football telecasts promoted this procompetitive objective. *Id.* at 117-20. The Supreme Court accepted that the defendants' asserted goal – promoting amateurism – was a legitimate procompetitive objective, but rejected NCAA's justification

because the "specific restraints on football telecasts" were "not even arguably tailored to serve such an interest." *Id*. at 117-18.

In *National Society of Professional Engineers v. United States*, 435 U.S. 679 (1978), the challenged restraint was a single provision in the defendant's code of ethics, which barred members from discussing fees with prospective clients until after they had been hired. *Id*. at 682-83. The Supreme Court did not consider procompetitive benefits flowing from the ethics code as a whole; instead, it focused on whether the specific challenged provision served a legitimate objective. *Id*. *See also FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447 (1986) (considering only whether the challenged restraint, not the broader "work rule" as a whole, furthered a procompetitive objective).

Similarly, in *North Texas Specialty Physicians v. FTC*, 528 F.3d 346 (5th Cir. 2008), the defendant sought to justify its anticompetitive pricing activities for its primary, fee-for-service payor contracts on the basis that this conduct promoted "spillover" efficiencies by attracting providers who participated in NTSP's other, risk-based contract. *Id.* at 368. Affirming the Commission, the Fifth Circuit assumed that these "spillover" benefits were legitimate, but held they did not justify the challenged conduct because "NTSP has no theory as to how its proffered procompetitive effects . . . result from or are in any way connected to" the anticompetitive pricing practices. *Id*. at 369.

In sum, a legitimate pro-competitive justification must be both logically connected to the restraint[7] and necessary to achieve the alleged benefit.[8]

Here, the challenged terms are the *payments for delay* from Cephalon to Ranbaxy. The challenged term *is not* the fact of the settlement. Plaintiffs *do not* challenge Ranbaxy's decision to settle the patent litigation, nor the general right of parties involved in Hatch-Waxman litigation to settle, nor the parties' right to enter into an unrelated, fair value supply agreement. *Actavis* specifically recognizes that Hatch-Waxman settlements are possible without payments for delay. *Id.* at 158 ("They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration,

[7] *Realcomp II, Ltd. v. F.T.C.*, 635 F.3d 815, 835 (6th Cir. 2011) (defendant's "free-riding justification fails" where defendant "has not demonstrated a connection between the website policy of [prohibiting certain listings from being publicly distributed] and the prevention of free-riding") (footnote omitted); *Law v. Nat'l Collegiate Athletic Ass'n*, 134 F.3d 1010, 1024 (10th Cir. 1998) (rejecting defendant's proffered procompetitive justification for a challenged restriction which limited the earnings of certain college coaches, somehow improved "competitive balance" because "the REC Rule is not directed towards competitive balance nor is the nexus between the rule and a compelling need to maintain competitive balance sufficiently clear on this record to withstand a motion for summary judgment"); *Rome Ambulatory Surg. Ctr. v. Rome Mem'l Hosp.*, 349 F. Supp. 2d 389, 410 (N.D.N.Y. 2004) ("The logical disconnect in defendants' argument is sufficient to raise a question of fact as to its justification."); *Brown v. Pro Football, Inc.*, 812 F. Supp. 237, 238 (D.D.C. 1992) ("two pro-competitive purposes advanced by the defendants — enhanced competition in the labor market for professional football players and the creation of otherwise unavailable football employment opportunities — were irrelevant for *lack of correlation* between the restraints and the pro-competitive purposes.").

[8] *Graphic Prods. Distribs., Inc. v. ITEK Corp.*, 717 F.2d 1560, 1577 (11th Cir. 1983) (affirming a jury verdict in favor of plaintiff) ("The goal of adequate and efficient service in territories beyond the branch office location was legitimate and pro-competitive, but there was no showing — nor any serious attempt to show — that the territorial restrictions were *reasonably necessary* to achieve that legitimate purpose."). *Cf. NASL v. NFL*, 670 F.2d 1249, 1261 (2d Cir. 1982) (defendant NFL had failed to prove the "market necessity" of its ban on team owners also owning soccer teams, and "[m]oreover, the NFL was required to come forward with proof that any legitimate purpose could not be achieved through less restrictive means. This it has failed to do."); *id.* at 1255 (reversing district court which had sat as factfinder in a non-jury "lengthy [bench] trial" on motion for injunction).

without the patentee paying the challenger to stay out prior to that point."). If Ranbaxy wanted to avoid the expense or risk of litigation – *i.e.,* its purported procompetitive justification - it could have negotiated a settlement without a payment in the manner described by *Actavis*. In such a no-payment settlement, Ranbaxy still could have benefitted financially – but in a procompetitive way by negotiating an earlier entry date, just as the Supreme Court stated. .[9]

This principle is also reflected in the ancillary restraint doctrine, which requires a defendant to show that the ancillary restraint was a necessary part of a procompetitive agreement. *See Major League Baseball Props., Inc. v. Salvino, Inc*., 542 F.3d 290, 338-39 & n.6 (2d Cir. 2008) (Sotomayor, J., concurring in the judgment); *Polk Bros., Inc. v. Forest City Enters., Inc.*, 776 F.2d 185, 189 (7th Cir. 1985). "[U]nder established precedent, a restraint is only ancillary if it is necessary to achieve otherwise unattainable procompetitive benefits." *In re Sulfuric Acid Antitrust Litig*., 743 F. Supp. 2d 827, 872 (N.D. Ill. 2010). When the restraint is not plausibly necessary to achieve the claimed benefits of an agreement, the benefits are not considered. *See Blackburn v. Sweeney*, 53 F.3d 825, 828 (7th Cir. 1995) (condemning reciprocal agreement not to advertise in each other's territory because restraint was not ancillary to the procompetitive dissolution of the partnership).

Applying these traditional antitrust principles, *Actavis* makes clear that, to be justified, the inclusion of a reverse payment *cannot be for delay*, but rather, for a legitimate, procompetitive objective beyond the general benefits of the settlement. As the Court explained:

[9] Two recent decisions discussing litigation risk as a defense failed to cite or consider the bedrock requirements that the asserted defense must explain the challenged term, rather than the agreement generally, and be necessary to the asserted benefit. *See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig*., 2018 U.S. Dist. LEXIS 18979, at *26 (D. Mass. Feb. 6, 2018) (following this Court's decision); *In re Impax Labs., Inc*., 2018 FTC LEXIS 82, at *224 (F.T.C. May 18, 2018) (appeal pending).

> An antitrust defendant … may show "that legitimate justifications are present, thereby explaining the presence of the ***challenged term*** and showing the lawfulness of that term under the rule of reason." *Id*. at 156 (emphasis added).

See also id. at 158 ("[O]ne who makes such a payment may be unable to explain and to justify it."). On remand, the *Actavis* district court understood this concept, properly concluding that the defendants had the burden "to justify the payments as being procompetitive." *In re Androgel Antitrust Litig.*, 2018 U.S. Dist. LEXIS 99716, *43 (N.D. Ga. June 14, 2018). *See also King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 412 (3d Cir. 2015)("*Lamictal*")(to establish a justification, the defendant must "show that the challenged conduct promotes a sufficiently pro-competitive objective"). Indeed, this Court itself correctly recognized that the defendant's burden is to justify the payment in its summary judgment decision. *See King Drug Co. v. Cephalon, Inc*., 88 F. Supp. 3d 402, 414 (E.D. Pa. 2015) (at justification stage of rule of reason, "defendants are given the opportunity to show that the payment was justified by a procompetitive objective").

As the Court noted, it is "fair game" for Ranbaxy to try to justify the reverse payment as accounting for "avoided-litigation costs" or "fair value for services." Ex. K (6/28/2017 Tr. at 88:7-12).[10] What Ranbaxy cannot do, however, is attempt to justify the payment by saying the agreement as a whole resolved patent litigation, without explaining why its goal of avoiding risk necessitated a reverse payment for delay. In other words, the dispute centers not on the settlement but on the alleged payment for delay. Ranbaxy must explain and justify that aspect of

[10] Of course, as this Court recognized, "fair value" is not a silver bullet under the rule of reason. Even if an antitrust defendant proffers cognizable, non-pretextual procompetitive justifications for the payment, the third step of the rule of reason provides that the jury must still weigh such justifications against the harm to competition, *i.e.*, higher prices resulting from delayed generic entry. *See King Drug*, 88 F. Supp. 3d at 419 ("Nowhere in *Actavis* does the Supreme Court suggest that fair market value is a silver bullet against antitrust scrutiny") (quoting *In re Nexium Antitrust Litig.*, 42 F. Supp. 2d 231, 263-64 (D. Mass. 2014)).

the agreement. But Ranbaxy could have settled without accepting a payment to delay entry until 2012. Because Ranbaxy's defense fails the required legal standards, and invites the risk of confusing the jury as to what Ranbaxy's burden is under the rule of reason, the Court cannot permit it.

Motion *in Limine* No. 19: To Preclude Ranbaxy From Asserting "Business Reasons" as Permissible Procompetitive Justification

Ranbaxy should be precluded from submitting evidence and argument that the Ranbaxy's actions were justified due to supposed "business reasons."[11] This Court itself instructed the jury that the rule of reason analysis is restricted to "the likely benefits and harm to competition and consumers, not just to a single competitor or a group of competitors." Ex. L (7/5/17 Tr. at 47:9-11). *See also Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977) ("The antitrust laws… were enacted for the protection of competition not competitors."). Accordingly, Ranbaxy's "business reasons" argument or that it made "business sense" to settle does not pose a pro-competitive justification. *See also United States v. Masonite Corp.*, 316 U.S. 265, 276 (1942) ("the fact that there were business reasons which made the arrangements desirable" was not a justification for a patent settlement that fixed prices); *Freeman v. San Diego Ass'n of Realtors*, 322 F.3d 1133, 1152 n.24 (9th Cir. 2003) ("It does not matter that Fallbrook and Valley Center would have operated at a loss in a competitive environment. Their precarious financial situation may have explained their intransigence, but it does not transform it into a viable defense. If there is any argument the Sherman Act indisputably forecloses, it is that price fixing is necessary to save companies from losses they would suffer in a competitive market."); *LePage's Inc. v. 3M*, 324 F.3d 141, 163 (3d Cir. 2003) (defense that defendant was merely "act[ing] in furtherance of

[11] As noted *supra*, Plaintiffs seek reconsideration of the Court's previous decision to permit Ranbaxy to assert a litigation risk defense. With respect to this motion *in limine*, however, Plaintiffs have not previously made a motion as to Ranbaxy's other asserted "business reasons."

its economic interests does not constitute the type of business justification that is an acceptable defense to § 2 monopolization"); *Meijer Inc. v. Barr Pharms., Inc.*, 572 F. Supp. 2d 38, 63 n.24 (D.D.C. 2008) ("Although the Court does not reach the merits of Barr's proffered procompetitive benefits, the Court notes that 'benefits' are only procompetitive when they promote and protect competition, not competitors . . . and when they do not rely on the assumption that competition itself is unreasonable.") (citations omitted).

Several of Ranbaxy's defenses at the 2017 trial (which will likely be asserted again) impermissibly focused on what was good for Ranbaxy, rather than good for competition. *First*, Ranbaxy argued that it would not make as much money if it prosecuted the patent suit to victory, because a win would allow other generics to enter, and Ranbaxy wouldn't make as much money with other sellers of modafinil on the market. *See, e.g.*, Ex. B (7/6/17 Tr. at 24:13-27:3) (Ranbaxy's closing argument). For instance, Venkatachalam Krishnan, Ranbaxy's former Regional Director for North America testified that competition among the generics resulting from Ranbaxy's continued litigation of the patent suit would mean Ranbaxy would not "recover[]" its "investment" if it pursued the patent litigation. Ex. K (6/28/17 Tr. at 124:24 – 125:13). Even assuming Ranbaxy were to make less money because other generics entered, litigating the case to completion would be procompetitive because it would increase competition among producers and lower prices for all purchasers.

Second, Ranbaxy also impermissibly sought to use its own supposed "poor financial situation," (Ex. B (7/6/17 Tr. at 16:8-10)), as a defense, although that does not bear on whether its actions were legal. *See also* Ex. K (6/28/17 Tr. at 104:22 – 105:6) (asserting Ranbaxy's "financial distress" as a factor justifying a settlement). Again, harm to Ranbaxy is not the issue – the question is whether any payment for delay harmed or benefitted competition. As the Court

instructed, "the likely benefits and harm to competition and consumers, not just to a single competitor or group of competitors."[12] *See* Ex. L (7/5/17 Tr. at 47:9-11).

Finally, Ranbaxy continues to assert that from a business standpoint that it was risky to lose the patent litigation. *See, e.g.*, Ex. K (6/28/17 Tr. at 104:22 – 105:6). Ranbaxy appears set to re-call Mr. Peter Ludwig, an attorney, who was previously proffered concerning "the risk and expense of patent litigation," (Ex. M (6/29/2017 Tr. at 105:6-17)), and whether it would make business sense for Ranbaxy to settle its patent case even if it were strong. *Id.* at 129-59. Ranbaxy's desire to avoid the risk of litigation and its alleged financial concerns do not constitute valid procompetitive justifications for the payment it received in connection with foregoing its patent challenge and delaying entry.

Motion *in Limine* No. 20: To Preclude Improper Argument or Evidence Concerning the Meaning of "Large" Payment

During opening statements in the 2017 trial, Ranbaxy's counsel improperly told the jury that the $26 million in reverse payments Ranbaxy received was not sufficiently "large" because the payment should be compared against various (massive) metrics that are completely irrelevant to the applicable standard under antitrust law. Ignoring the express language of the Court's summary judgment decision on this very issue, Ranbaxy argued (among other things) that the payment it received was not "large" enough because it should be examined in relation to:

(1) the entire "worldwide pharmaceutical market" of "600 billion";

(2) the total branded "Provigil sales" of "$5.7 billion"; and

[12] *See U.S. v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 221 (1940) (claims of "[r]uinous competition, financial disaster, [and] evils of price cutting" are not cognizable defenses to price fixing); *Freeman,* 322 F.3d at 1152 n.24 ("If there is any argument the Sherman Act indisputably forecloses, it is that price fixing is necessary to save companies from losses they would suffer in a competitive market.").

(3) the total that Cephalon paid to all the generic manufacturers in the amount of "$300 million."

See Ex. A (6/14/2017 Tr. at 111:5-116:25).

Immediately thereafter, the Court held a sidebar and noted that Ranbaxy's statements to the jury took the determination of large "completely out of [] context" from the applicable legal standard under *Actavis*, and created a "pretty crucial" issue. *Id.* at 139:10-141:14. The Court also instructed that 2017 Plaintiffs should have objected to these "improper" statements, notwithstanding the fact that the offending statements were made during opening, because "now we have this problem everyone is concerned about." *Id.;* Ex. D (6/26/2017 Tr. at 26:13-27:6). 2017 Plaintiffs then filed a mid-trial motion *in limine* to address the topic, (*see* Case No. 06-cv-2768, Dkt No. 1236), which was not expressly ruled on by the Court. Instead, the Court addressed the issue through the jury instructions (as set forth in relevant part below), which incorporated the standard articulated by the Court on summary judgement, not the extraneous and prejudicial measures improperly argued by Ranbaxy.

Plaintiffs here seek to prevent this same "crucial" issue from arising in their trial. Ranbaxy should be barred from presenting its prior improper arguments, as well any other arguments or evidence that are similarly unmoored from, or inconsistent with, the applicable legal standard of "large" as provided by the Court's 2015 summary judgement decision and 2017 Final Jury Instructions.

A. The Legal Standard for a "Large" Payment is One that Exceeds Saved Litigation Costs and is Merely Significant Enough to Induce the Generic to Stay Off the Market

In its summary judgment opinion, this Court carefully set forth the standard governing Plaintiffs' claims under the framework dictated by the Supreme Court in *Actavis*. *See King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 411-18 (E.D. Pa. 2015). In so doing, the

Court specifically addressed "What Constitutes a Large Payment?" *Id.* at 417-18. The Court explained that "a reverse payment is sufficiently large *if it exceeds saved litigation costs and a reasonable jury could find that the payment was significant enough to induce a generic challenger to abandon its patent claim*." *Id.* (discussing *Actavis*, 133 S.Ct. at 2234–37) (emphasis added). The Court then concluded that proving the existence of a large payment is part of Plaintiffs' "initial burden" under the rule of reason burden-shifting framework. *Id.* at 405, 415, 418.[13]

In so ruling, the Court expressly rejected Defendants' argument that other measures could serve as an "appropriate benchmark" for "large" - including "the brand manufacturer's expected monopoly profits." *King Drug*, 88 F. Supp. 3d at 417-18. "As *Actavis* explains, the relevant inquiry is what would induce the generic to stay off of the market." *Id.* (citing *Actavis*, 133 S.Ct. at 2235) (emphasis in original). Indeed, the inquiry of whether the payment was large enough to induce the generic to abandon its efforts to enter the market is the very linchpin of the *Actavis* analysis. *Actavis*, 133 S. Ct. at 2234-35 (holding that "the specific restraint at issue has the 'potential for genuine adverse effects on competition" because "[t]he payment may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market") (citation omitted).[14]

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[13] The correctness of this Court's conclusion was confirmed by the Third Circuit in *Lamictal*. *See Lamictal*, 791 F.3d at 412 & n. 37 (citing *King Drug*, 88 F. Supp. 3d at 411-20).

[14] *Actavis* itself rejected the notion that the size of the reverse payment should be judged by the revenues that the brand company stood to lose to generic competition. The Eleventh Circuit had held that: "When hundreds of millions of dollars of lost profits are at stake, 'even a patentee confident in the validity of its patent might pay a substantial sum in settlement.'" *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1313 (11th Cir. 2012) (citation omitted). In reversing, the Supreme Court specifically rejected this purported justification: "The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment.

In its 2017 Final Jury Instructions, this Court reaffirmed that the standard set forth in its summary judgment opinion governs the "large" payment inquiry to be performed by the jury. The Court thus instructed the jury that a reverse payment is sufficiently "large" if it meets the following criteria:

> First, you must ask whether the payment exceeds the patent holder's-here, Cephalon's anticipated future litigation costs.
>
> Second, you must consider whether the payment was significant enough to induce a generic challenger - here, Ranbaxy - to abandon its patent claim and stay off the market. One factor you may consider in assessing whether the payment was significant enough to induce Ranbaxy to stay off the market, is whether the payment comes close to or exceeds the expected profit to be earned by Ranbaxy if it had prevailed in the patent litigation.

See Ex. N (Final Jury Instructions at No. 9) ("Rule of Reason – Plaintiffs' Initial Burden – Whether the Payment was 'Large'") (citing *King Drug Co.*, 88 F. Supp. 3d at 416-18).

The Third Circuit - both before and after the 2017 Ranbaxy trial - has agreed that "large" is not an absolute quantitative measure, but is, rather, ultimately qualitative once the initial threshold of the brand's saved future litigation costs is met. For example, in *Lamictal*, the Third Circuit held that non-cash forms of payment, such as agreeing not to launch an authorized generic (or "AG") version of the drug at issue for a period of time after the generic launches, can be

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But, be that as it may, the payment (if otherwise unexplained) likely seeks to avoid the risk of competition. And, as we have explained, that consequence constitutes the relevant anticompetitive harm." 133 S. Ct. at 2236. The Supreme Court also explained that defendants could be liable even if the reverse payment could have been recouped by the brand:

> Solvay's patent, if valid and infringed, might have permitted it to charge drug prices sufficient to recoup the reverse settlement payments it agreed to make to its potential generic competitors. And we are willing to take this fact as evidence that the agreement's anticompetitive effects fall within the scope of the exclusionary potential of the patent. But we do not agree that that fact, or characterization, can immunize the agreement from antitrust attack.

133 S. Ct. at 2230 (citation omitted).

unlawful under *Actavis*. *See Lamictal*, 791 F.3d at 409-10. The court wrote, "Because marketing an authorized generic was allegedly in GSK's economic interest, its agreement not to launch an authorized generic *was an inducement*—valuable to both it and Teva—to ensure a longer period of supracompetitive monopoly profits based on a patent at risk of being found invalid or not infringed." *Id*. (emphasis added). Stated plainly, it was a "transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition." *Id*. at 394. Likewise, in the weeks following the 2017 trial, the Third Circuit again found that a non-cash agreement to release claims from a separate litigation could constitute a "large" payment because the value obtained therefrom could have been "an inducement" for the generic to abandon the patent challenge on the drug at issue.

In re Lipitor Antitrust Litig., 868 F.3d 231, 253–54 (3d Cir. 2017). *Accord* Phillip E. Areeda & Herbert Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 2046d6 (3rd and 4th Editions, 2018 Cum. Supp. 2010-2017) ("The *Actavis* decision *does not require evidence of a payment of a particular size, but only a payment in excess of reasonably anticipated litigation costs*.") (emphasis added).

There can thus be little dispute that under the law as repeatedly stated by this Court, the Third Circuit, and the Supreme Court in *Actavis*, whether a reverse payment is "large" for antitrust purposes is determined in relation to: (1) the brand company's saved future litigation costs in the patent litigation; and (2) an inducement for the generic manufacturer to stay off the market. As to the latter, the relevant consideration is "whether the payment comes close to or exceeds the expected profit to be earned *by Ranbaxy if it had prevailed in the patent litigation*." *See* Ex. N (2017 Final Jury Instructions at No. 9) (emphasis added); *King Drug Co.*, 88 F. Supp. 3d at 417 (citing Herbert Hovenkamp, Anticompetitive Patent Settlements and the Supreme

Court's Actavis Decision, 15 Minn. J.L. Sci. & Tech. 3, 12 (Winter 2014) ("Even if the generic believes there is a 100% likelihood that the patent will be found invalid, it may still be more valuable for the generic to share the monopoly returns")). Any arguments to the jury outside the parameters of this applicable standard can only be improper.

B. Ranbaxy's Contrary Arguments to the Jury in the 2017 Trial Were Irrelevant, Misleading, Confusing, Highly Prejudicial, and Should Be Precluded from This Trial

Ranbaxy sought to avoid liability at the 2017 trial by having the jury instead compare the size of the reverse payment Ranbaxy received to various huge – and hugely irrelevant – numbers. Ranbaxy primarily argued, for example, that "the worldwide pharmaceutical market" provided the relevant measure:

> The first thing I would like you to look at is you are going to hear from an esteemed doctor in economics. His name is Dr. Bell, and he is going to tell you that the worldwide pharmaceutical market at the time of this settlement was 600 billion, that is with a b, in sales. That is the size of worldwide. Right here. 600 billion, 6.5 billion. That is how big the worldwide pharmaceutical market was in 2005.
>
> If you take Plaintiffs' number, which I disagree with, as I have said, of 26 million that they claim my client was paid and you divide it by that 600 million -- or billion, I should say, statistically, my client was paid 0 percent of the worldwide financial -- of the worldwide pharmaceutical market.

Ex. A (6/14/2017 Tr. at 113:10-23).

Then - notwithstanding the fact the Court had already held on summary judgment that the branded manufacturer's expected revenues is an inappropriate benchmark (*see supra*) - Ranbaxy's counsel proceeded to inappropriately tell the jury that the payment was similarly not "large" because it should also be measured against "$5.7 billion in Provigil sales:"

> So if you take their number, what [Cephalon] paid us, 26 million, and you divide it by 5.7 billion, 5.7 billion in Provigil sales -- and I want to get this right -- that comes out to .0045, less than a half of a percent. Less than one half of a percent.
> . . . .

> If you do the same math . . . that is zero percent statistically of the worldwide pharmaceutical industry. That is one-third of 1 percent of Cephalon's 5.7 billion in sales. . . . So what their theory is, is that for one-third of 1 percent, that is a large payment to keep my client, a generic company, Ranbaxy, away from their $5.7 billion franchise. First of all, that is not large.

Id. at 114:7-11; 116:13-24.

Still not done, Ranbaxy's counsel further urged the jury to determine "large" in relation to the total pool of reverse payment dollars that Cephalon paid out to the generic manufacturers collectively:

> [T]he total amount of payments from Cephalon to these settling generic defendants was $300 million. . . .
>
> Now, if we do the math of how much was 26 million to my client divided by the 300 million, what percentage did Ranbaxy receive of the overall payments made by Cephalon, even if we take their $26 million number? Well, the answer is 8.6 percent to Ranbaxy. That means what, 92.4 percent, 93.4 percent went to somebody other than Ranbaxy.
>
> In this context, when 93 percent of the money paid by Cephalon went to Teva, Mylan and Barr and not to Ranbaxy in the context of the pharmaceutical industry, these big deals, is that a large payment? I'll tell you the evidence is going to show you just that and it is not large.

Id. at 115:4-22.[15]

As noted by the Court at the time, Ranbaxy's statements took the requirement of a "large" payment "completely out of context," were "improper," and went to a "pretty crucial" issue of proof. *Id.* at 139:10-141:14; Ex. D (6/26/2017 Tr. at 26:13-27:6).

[15] Ranbaxy's counsel later touted their improper arguments in an ABA Antitrust article as having created a precedent for antitrust defendants, stating that "*Modafinil* is also noteworthy because the defendant was permitted to offer evidence comparing the alleged size of the reverse payment to the brand's profits for the patented product." *See* Lisa Jose Fales et al., *Welcome to the Wild, Wild West: Actavis Five Years Later*, Antitrust (ABA), Summer 2018, Vol. 32, No. 3 at 19. As shown above, this is the opposite of what the Court held on summary judgment and ultimately permitted in the final jury instructions.

Such arguments (and referenced facts or evidence used in relation thereto) are not only irrelevant, but plainly violate Federal Rule of Evidence 403 as confusing the issues, misleading the jury, and creating undue prejudice to Plaintiffs in terms of the true and proper standard that must be met to prevail on their claims. *See, e.g.*, *United States v. Robertson*, 875 F.3d 1281, 1296 (9th Cir. 2017) (holding that materials presenting "standards and considerations" that "were not the same as the jury instructions, *i.e.*, the law that the jury had to follow" were properly excluded as creating "danger of confusing the issues and misleading the jury"; "the court provides the law to the jury"); *In re: Tylenol (Acetaminophen) Mktg., Sales Practices, & Prod. Liab. Litig.*, 2016 U.S. Dist. LEXIS 99177, at *32 (E.D. Pa. July 28, 2016) (excluding presentation of a different "legal standard of care" as "such information could mislead the jury").

Ranbaxy should therefore be precluded from repeating what the Court previously deemed "improper" comparisons or statements to the jury as to what constitutes a "large" payment, as well any other arguments or evidence that are similarly irrelevant to, or inconsistent with, the applicable legal standard as provided by the Court in both its 2015 summary judgment decision and 2017 Final Jury Instructions.

Motion *in Limine* No. 21: To Permit Plaintiffs to Quantify Harm to Competition During Plaintiffs' Opening Statements

Before opening statements in the 2017 trial, Ranbaxy orally asked the Court to preclude 2017 Plaintiffs from "quantifying" for the jury the "harm to competition" or "harm to consumers" that 2017 Plaintiffs would show in their case. Ex. A (6/14/2017 Tr. at 10:4-12:2). Without the benefit of briefing on the subject, the Court sustained Ranbaxy's objection, "[b]ut just for openings," until the Court "understand[s] the case better," because the Court was "not comfortable with it now." *Id.* at 12:3-17. After the trial developed, however, and over the same objections by Ranbaxy, the Court allowed 2017 Plaintiffs' expert, Dr. Hal Singer, to testify that

the agreements at issue resulted in harm to competition and consumers in the amount of "billions of dollars," as calculated by Dr. Singer. *See* Ex. K (6/28/2017 Tr. at 45:6-49:15; Ex. M (6/29/2017 Tr. at 14:3-16:13).

Plaintiffs respectfully submit that Ranbaxy's objection to such quantification in opening statements in the 2017 trial was unfounded and should not have been sustained, as ultimately recognized in the Court's ruling allowing such quantification through Dr. Singer's testimony. Likewise, prohibiting Plaintiffs here from referencing in opening (or later eliciting) this directly relevant evidence would serve no purpose other than to significantly and unfairly handicap Plaintiffs with respect to proving the central issues placed to the jury—including whether the challenged agreement produced substantial harm to competition, and whether such harm outweighs any claimed procompetitive benefits.

As provided in the Court's Final Jury Instructions in the 2017 trial (and as previously articulated on summary judgment), under the rule of reason, Plaintiffs bear the initial burden of showing that the payment produced "anticompetitive effects" or "substantial harm to competition." *See* Ex. N (2017 Final Jury Instructions at No. 7 ("Rule of Reason"); No. 8 ("Rule of Reason – Plaintiffs' Initial Burden")). The burden then shifts to Ranbaxy to show procompetitive benefits of the payment. If Ranbaxy meets its burden of establishing the existence of procompetitive benefits, and Plaintiffs fail to show that the claimed benefits could have been achieved by other, less harmful means, the jury then:

> must balance those procompetitive benefits against the competitive harm. If the competitive harm substantially outweighs the likely procompetitive benefits, then the challenged restraint is unreasonable. In conducting this analysis, you must consider the likely benefits and ***harm to competition and consumers***, not just to a single competitor or group of competitors.

See Ex. N (2017 Final Jury Instructions at No. 17 ("Rule of Reason – Weighing") (emphasis added)).[16] *Accord King Drug*, 88 F. Supp. 3d at 412 ("The fact-finder then *weighs all of the effects* and circumstances of the case and *determines if the agreement is, on balance, anticompetitive*.") (citing *Pa. Dental Ass'n v. Med. Svc. Ass'n of Pa.*, 745 F.2d 248, 255 (3d Cir.1984)) (all emphases added)). Indeed, in Ranbaxy's own proposed jury instructions, it conceded this legal requirement that the jury consider and weigh the "harm to competition and consumers." *See* Ex. O (Ranbaxy's Proposed Final Jury Instructions at No. 19 ("Sherman Act Section 1– Balancing the Competitive Effects") ("[Y]ou must consider the benefits and harm to competition and consumers")).

Quite simply, the jury cannot fairly weigh the anticompetitive harm of the conduct at issue against any claimed procompetitive benefits if the jury is prohibited from hearing or understanding the *magnitude* of that harm. Ranbaxy should not be permitted to place its thumb on the scale in the rule of reason balancing by precluding the fact-finder from hearing the extent of the adverse effects that its conduct had on competition and consumers - which is precisely what the jury is charged with considering.[17] Nor is the jury somehow limited to considering anticompetitive harm in the abstract.

Ranbaxy previously offered two apparent justifications for its position seeking to handcuff plaintiffs at trial—both of which are without merit. First, Ranbaxy argued that

[16] Plaintiffs reserve the right to object to a jury instruction providing that the competitive harm must "substantially" outweigh the likely procompetitive benefits.

[17] Under *Hanover Shoe, Inc. v. United Shoe Mach. Corp*., 392 U.S. 481 (1968) and *Ill. Brick Co. v. Illinois*, 431 U.S. 720 (1977), under federal law direct purchasers stand in the shoes of the entire market and are entitled to recover under the Clayton Act the full amount of the anticompetitive harm they suffered.

"quantifying" the anticompetitive harm in Phase One would be unfairly prejudicial. *See* Ex. A (6/14/2017 Tr. at 11:12-12:2).

But this argument plainly misconstrues the rule of reason analysis for determining whether the restraint at issue amounts to an antitrust violation, as discussed above. The Court did indeed limit the first phase of trial of these matters to the "proofs regarding the alleged antitrust violation under the rule of reason." *Apotex, Inc. v. Cephalon, Inc.*, 255 F. Supp. 3d 604, 614–15 (E.D. Pa. 2017). Those proofs, however, involve precisely what Ranbaxy does not want the jury to hear. The ultimate inquiry of the rule of reason analysis necessarily requires that the fact-finder "weighs *all of the effects*," and "determines if the agreement is, on balance, anticompetitive." *King Drug*, 88 F. Supp. 3d at 412 (citing *Pa. Dental Ass'n,* 745 F.2d at 255) (emphasis added); Ex. N (2017 Final Jury Instructions at Nos. 12, 17). Showing the extent or amount of harm to competition is therefore directly relevant—and indeed, critical—to proving an antitrust violation under the rule of reason.

Second, Ranbaxy argued that quantifying the harm to competition through harm to "consumers" was improper and "inflammatory" since 2017 Plaintiffs were "not representing consumers." Ex. K (6/28/2017 Tr. at 45:6-49:15); Ex. M (6/29/2017 Tr. at 14:3-16:13). Again, this makes no sense in the context of the law. As stated by the Third Circuit, "Antitrust law is *designed to protect consumers* from arrangements that prevent competition in the marketplace." *Lamictal*, 791 F.3d at 405 (citing *Actavis*, 133 S. Ct. at 2234–35)(emphasis added)). It has therefore long been true that "anticompetitive effects" or "harm to competition" focuses primarily on "harm to consumers"—regardless of whether the individual plaintiff itself is a consumer. *See, e.g.*, Phillip E. Areeda & Herbert Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶1503. (3rd and 4th Editions, 2018 Cum.

Supp. 2010-2017) (competitive harm is best defined as a "consumer welfare" test "that considers *principally harms to consumers*") (emphasis added)). Indeed, as recently stated by the Supreme Court, a plaintiff under the rule of reason framework must "prove that the challenged restraint has a substantial anticompetitive effect *that harms consumers*." *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018) (emphasis added). There is no difference in the pay-for-delay arena: "In the *Actavis* Court's view, reverse payments are problematic because of their potential to negatively impact *consumer welfare* by preventing the risk of competition." *Lamictal.*, 791 F.3d at 403-04 (citing *Actavis*, 133 S. Ct. at 2236) (emphasis added). Thus, as succinctly and correctly noted by counsel for Apotex before the Court overruled Ranbaxy's objections to Dr. Singer's testimony, "That is the legal test." Ex. K (6/28/2017 Tr. at 48:22-49:15). And, as further reasoned by the Court, anticompetitive effects do not occur "in a vacuum," and it is commonly known and understood that competitive harm is felt "by the person who buys the product, the consumers." *Id.*

For these reasons, the Court's 2017 Final Jury Instructions, as well as Ranbaxy's own proposed jury instructions, expressly provide that the jury "must" consider the harm "*to consumers*" in evaluating the restraint in the rule of reason analysis. Ex. N (Final Jury Instructions at No. 17); Ex. O (Ranbaxy's Proposed Final Jury Instructions at No. 19) (emphases added).

Any prejudice to Ranbaxy from the jury hearing the extent or amount of such harm produced by Ranbaxy's conduct therefore cannot be "unfair," as required for exclusion under Rule 403. To be "unfair," prejudice must arise from an "undue tendency to suggest decision *on an improper basis*" - not the very facts the jury is instructed to weigh and consider. Fed. R. Evid. 403 advisory committee notes (emphasis added). Prejudice in this sense "'does not simply

mean damage to the opponent's cause.' If it did, most relevant evidence would be deemed 'prejudicial.' However, the fact that probative evidence helps one side prove its case obviously is not grounds for excluding it under Rule 403. Excluded evidence must be unfairly prejudicial, not just prejudicial." *Goodman v. Pennsylvania Tpk. Comm'n*, 293 F.3d 655, 670 (3d Cir. 2002) (quoting 1 McCormick on Evidence § 185 at 645 (John W. Strong, et al. eds., 5th ed.1999)).

Plaintiffs should thus be permitted to reference during opening statements the amount of anticompetitive harm produced by the conduct at issue, which will be properly presented through admissible expert witness testimony at trial. Such information is fairly and squarely before the jury - and indeed must be considered in the relevant inquiries for determining the legality of Ranbaxy's conduct under the rule of reason test.

Motion *in Limine* No. 22: To Exclude the Proffered Expert Testimony of Louis Berneman

During the 2017 trial, Ranbaxy proffered and presented the expert testimony of Louis Berneman on: (a) the API supply agreement between Cephalon and Ranbaxy; and (b) the IP licensing agreement between Cephalon and Ranbaxy. *See* Ex. E (6/27/2017 Tr. at 52:1 – 223:17). United has joined in and adopted the prior *Daubert* motion filed by the FTC and the King Drug Plaintiffs on April 4, 2014 to exclude the testimony of Louis Berneman. *See* Case No. 08-2141, Dkt No. 278. In addition, both United and King Drug plaintiffs adopt the *Daubert* motion filed by Apotex to exclude the testimony of Louis Berneman. *See* Case No. 06-2768, Dkt. 700.

While the Court denied the foregoing motions, (*see* Case No. 06-2768, Dkt No. 1191), Plaintiffs respectfully request that the Court to reconsider its denials.[18] As shown in the prior motions, Dr. Berneman: (a) is not qualified to give an opinion on the risks posed to Cephalon's

[18] *See supra* at n. 6.

business by the putative Ranbaxy patents; (b) is not qualified to give an opinion on API supply issues; and (c) does not engage in a reliable methodology for either his opinions on API supply or IP licensing. Plaintiffs hereby seek to supplement the prior motions to emphasize the first two of these points.

First, in denying the motions seeking to exclude Dr. Berneman as unqualified to opine on the legal risk that Ranbaxy's modafinil IP posed to Cephalon's modafinil franchise, the Court held that Defendants made clear they "do not intend to solicit an independent opinion on the infringement risk from Dr. Berneman," and that this was "entirely consistent with Dr. Berneman's expert report which explicitly states that he is relying upon the expert reports and testimony of Dr. Myerson and Dr. John Mallamo when discussing the infringement risk." *See* Case No. 06-2768, Dkt. 1191 at ¶¶ 25-27. However, Drs. Myerson and Mallamo testified solely as to the infringement risk to Cephalon posed by the ***Teva*** IP, and did not address the Ranbaxy IP at all. Therefore, Dr. Berneman cannot rely on those experts for any opinion he may try to give about the Ranbaxy IP and the Cephalon-Ranbaxy IP deal. Moreover, contrary to the prior representations by Ranbaxy relied on by the Court, Dr. Berneman did indeed give expert testimony about the "infringement risk" Cephalon supposedly faced during the 2017 trial:

> "Q. What is the bottom line view on your opinion on the intellectual property license, sir?
>
> A. So in my view, again based on my experience, Cephalon paid a million dollars, and for that got insurance to protect the $500-plus million product and protected itself such that if Ranbaxy had a patent issue – if it hadn't – if it did not take the license and Ranbaxy's patent issued in the United States and it included claims for oral dosing of the particle size, then Ranbaxy would be in a position, if it chose to, to bring a patent infringement lawsuit against Cephalon, which would have cost a lot of -- a lot of money in legal fees, litigation costs to defend that lawsuit.
>
> And if Cephalon lost that lawsuit, that is if Cephalon [sic] prevailed and Cephalon's modafinil products were found to infringe the valid patent,

> then Ranbaxy could charge Cephalon what are called running royalties, which could have potentially been tens of millions of dollars, so pretty good insurance to protect a franchise product."

See Ex. E (6/27/2017 Tr. at 99:22 – 100:16).

Dr. Berneman went on to describe the Ranbaxy patents as "related to modafinil – processes for making modafinil, oral dosing for modafinil, and the processes would include the particle size issue that we have talked about." *Id.* at 102:4 – 7. In response to leading questions from Ranbaxy's counsel, Dr. Berneman then opined that there was no doubt in his mind that the IP licenses "were commercially reasonable" and not at all "atypical or unusual." *Id.* at 102:25 – 103:11. Yet Dr. Berneman has no expertise that would allow him to opine that the Cephalon-Ranbaxy IP was "pretty good insurance" and "commercially reasonable." That testimony is impossible to give without opining on the "infringement risk" the Ranbaxy IP posed to Cephalon. And Ranbaxy admits that Dr. Berneman has no expertise on patent infringement risk; that is why Ranbaxy had him rely on Drs. Myerson and Mallamo. But Dr. Myerson and Dr. Mallamo addressed infringement risk posed only by the ***Teva*** IP, not by the Ranbaxy IP, and that is what they are not expected to testify at this trial.

Dr. Berneman's opinion could only be relevant and reliable if it included an assessment of the infringement risk posed by the Ranbaxy IP. Dr. Berneman does not have expertise to give such an opinion. And he cannot rely on Drs. Myerson or Mallamo to give such an opinion because they never addressed Ranbaxy's IP.

Second, in denying the motions to exclude Dr. Berneman as a proffered expert on supply chain management, the Court found that "Dr. Berneman has been involved in supply chain management issues throughout his career…" Case No. 06-1768, Dkt. 1191 at ¶ 15. That is not correct. Dr. Berneman's experience with supply chain management issues is limited to his work

at two companies between 1982 and 1989. This is evident from his trial testimony. *See* Ex. E (6/27/2017 Tr. at 54:24 – 55:10) (testifying that his experience with supply chain management was at two companies, "Immuno Modulators Laboratories" and "Biotherapeutics Incorporated"); Case No. 06-2768, Dkt. 700, Ex. G (Berneman CV showing dates of his work at "Immuno Modulators Laboratories" as 1982-1984 and at "Biotherapeutics Incorporated" as 1984-1989). The Court relied on a misleading sentence from paragraph 2 of Dr. Berneman's report, stating: "I have been involved in supply chain management issues over the course of my career." Case No. 06-2768, Dkt. 1191 at ¶ 15 (citing Berneman Report at ¶ 2). The record shows that the entirety of Dr. Berneman's experience with supply chain management occurred between 1982 and 1989, and his limited experience with the supply of API was during this remote time period. This limited experience from early in Dr. Berneman's career roughly thirty or more years ago is insufficient to qualify Dr. Berneman as an expert in API supply chain management.[19]

Dated: August 23, 2018

Respectfully submitted,

/s/ Bruce E. Gerstein

BERGER & MONTAGUE, P.C.
David F. Sorensen
Daniel C. Simons
Nicholas Urban
1818 Market Street, Suite 3600
Philadelphia, PA 19103
Tel: (215) 875-3000
Fax: (215) 875-4604

GARWIN GERSTEIN & FISHER LLP
Bruce E. Gerstein
Joseph Opper
Kimberly Hennings
Wall Street Plaza
88 Pine Street, 10th Floor
New York, NY 10005
Tel: (212) 398-0055

[19] *See Surace v. Caterpillar, Inc.*, 111 F.3d 1039, 1055 (3d Cir. 1997) (affirming decision to exclude expert because proponent failed to show that he "possesses sufficient knowledge . . . , either through training or experience, to testify as an expert" on a specific issue); *XpertUniverse, Inc. v. Cisco Sys., Inc.*, 2013 U.S. Dist. LEXIS 31327, at *10 (D. Del. Mar. 7, 2013) (precluding opinions that "go beyond [the expert's] expertise and knowledge" into the "realm of speculation").

Fax: (212) 764-6620

HEIM PAYNE & CHORUSH, LLP
Russell Chorush
Heritage Plaza
1111 Bagby, Suite 2100
Houston, TX 77002
Tel: (713) 221-2004
Fax: (713) 221-2021

ODOM & DES ROCHES, LLP
Stuart E. Des Roches
650 Poydras Street, Suite 2020
New Orleans, LA 70130
Tel: (504) 522-0077
Fax: (504) 522-0078

SMITH SEGURA & RAPHAEL, LLP
Susan C. Segura
3600 Jackson Street, Suite 111
Alexandria, LA 71303
Tel: (318) 445-4480
Fax: (318) 487-1741

FARUQI & FARUQI LLP
Peter Kohn
101 Greenwood Avenue, Suite 600
Jenkintown, PA 19046
Tel: (215) 277-5770
Fax: (215) 277-5771

Counsel for King Drug Co. of Florence, Inc., Rochester Drug Co-Operative, Inc., Burlington Drug Co., Inc., J.M. Smith Corp. d/b/a Smith Drug Co., Meijer, Inc., Meijer Distribution, Inc., Stephen L. LaFrance Holding, Inc. Stephen L. LaFrance Pharmacy, Inc. d/b/a SAJ Distributors, Miami-Luken, Inc., McKesson Corporation, AmerisourceBergen Corp., AmerisourceBergen Drug Corp., Bellco Drug Co., H.D. Smith Wholesale Drug Company, Valley Wholesale Drug Co., LLC, Cardinal Health, Inc., Harvard Drug Group, L.L.C., FWK Holdings, LLC, Publix Super Markets, Inc., The North Carolina Mutual Wholesale Drug Company, and Value Drug Company

NASTLAW LLC
Dianne Nast
Erin Burns
1101 Market Street, Suite 2801
Philadelphia, PA 19107

ROBERTS LAW FIRM, PA
Mike L. Roberts
20 Rahling Circle
Little Rock, AR 72223

Counsel for Stephen L. LaFrance Holding, Inc. and Stephen L. LaFrance Pharmacy, Inc. d/b/a SAJ Distributors

VANEK VICKERS & MASINI, P.C.
Joseph M. Vanek
David Germaine
55 W. Monroe Street – Suite 3500
Chicago, IL 60603
Tel: (312) 224-1500
Fax: (312) 224-1510

Counsel for Publix Super Markets, Inc., FWK Holdings, LLC, Meijer, Inc. and Meijer Distribution, Inc.

/s/ Judith A. Zahid
ZELLE LLP
Judith A. Zahid
Jonathan M. Watkins
Eric W. Buetzow
44 Montgomery Street – Suite 3400
San Francisco, CA 94104
Tel: (415) 693-0700

/s/ Hamish P.M. Hume
BOIES, SCHILLER & FLEXNER LLP
Hamish P. M. Hume
William C. Jackson
Abby L. Dennis
Kyle Smith
1401 New York Avenue, NW
Washington, DC 20005
Tel: (202) 237-2727

ZELLE LLP
James R. Martin
Jennifer Duncan Hackett
1775 Pennsylvania Avenue, NW – Suite 375
Washington, DC 20006
Tel: (202) 899-4101

ZELLE LLP
Jonathan R. MacBride
401 Plymouth Road, Suite 120
Plymouth Meeting, PA 19462
Tel: (484) 532-5330

Counsel for United Healthcare Services, Inc.

CERTIFICATE OF SERVICE

I, Bruce E. Gerstein, hereby certify that on August 23, 2018, I caused Plaintiffs' Omnibus Motions *in Limine* Nos. 14-22, Declaration of Bruce E. Gerstein in Support of Plaintiffs' Omnibus Motions *in Limine* Nos. 14-22 (and exhibits thereto), and Proposed Order, to be filed with the Court's CM/ECF system, where the foregoing documents are available for downloading and viewing.

Dated: August 23, 2018 /s/ Bruce E. Gerstein